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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,987	10/01/2001	Andrew D. Murdin	032931-0253	7970

7590 05/23/2006

Bernhard D Saxe
Foley & Lardner
Suite 500
3000 K Street NW
Washington, DC 20007-5109

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,987	MURDIN ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/27/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-2, 4-17, 20-38, 79-83 are* is/are pending in the application.

4a) Of the above claim(s) *20-24, 26-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-17,25,36-38 and 79-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/06 has been entered.

Amendment

2. The amendment filed on 2/27/06 is entered.

Petition /Restriction

3. Applicant keeps on arguing about the restriction in spite of the decision made on applicant's petition. Since the petition for reconsideration of the restriction is not granted, the examiner is not able to respond or reconsider the arguments of record.

Status of claims

4. Claims 1, 2, 8, 9, 17, 25 and 27 have been amended. Please note Claim 2 is currently amended, however, it is represented as previously presented. This is an error. However, in order to advance the prosecution, the examiner has considered that as amended. Applicant is advised to carefully review the status of claims when submitting amendment to the claims.

Claims 3, 18-19, 39-78 have been canceled.

Claims 1-2, 17, 20-38, 79-83 are pending.

Claims 1,2, 4-17, 25, 36-38 (in part) and 79-83 are under prosecution with respect to DNA comprising SEQ.ID.NO: 1 and DNA encoding the SEQ ID NO: 14. Applicant is advised to amend claims to restrict to nucleic acid only.

Claims 20-24, 26-35 and 36-38 (in part) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Rejections - 35 USC 102 moot

5. In view of cancellation of claim 3, the rejection under 35 U.S.C. 102(b) as being clearly anticipated by Hillier et al (Genome Research. Vol 6, no 9, pages 807-828. 1996) is moot.

Claim Rejections - 35 USC 102 withdrawn

6. In view of clarification of 102 (e) date, the rejection under 35 U.S.C. 102(e) as being clearly anticipated by Griffais et al U.S.Patent 6, 559, 29 is withdrawn.

35 U.S.C. 112 written description rejection maintained

7. The written description rejection of claims 1,2, 4-17, 25, 36-38 (in part) and 79-83 under 35 U.5.C. 112, first paragraph is maintained as set forth in the previous office action.

The specification only describes the polynucleotide sequence of SEQ ID NO: 1. The specification describes as part of the invention-isolated polynucleotide encoding the polypeptide of SEQ ID NO: 14 (CPN 100686 RY 54), which is a "putative 98kDouter membrane protein (see pages 8-10). However, broadly claimed nucleic acid sequence which encodes a polypeptide SEQ.ID.NO: 14 variants/fragments, a nucleic acid comprising 38/100 consecutive nucleic acids, a nucleic acid sequence encoding an immunogenic fragments of 12/50 consecutive amino acids and a method of preventing infection using such nucleic acid is not set forth in this specification. Applicants also broadly describe the invention as embracing any substitution, insertion or deletion change of nucleotides throughout the entire stretch of nucleotides by use of language in which a specified percent of amino acids can be changed. As depending from these are the vectors, host cells, vaccines, diagnostics and methods of producing the polypeptide. None of these sequences meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The specification only discloses a polynucleotide sequence consisting of SEQ ID NO: 1 which corresponds to the polynucleic acid sequence encoding the Chlamydia pneumoniae protein which comprises the amino acid sequence SEQ ID N0: 14. Thus, an isolated polynucleotide sequence comprising the nucleic acid sequence SEQ ID NO: 1 meets the written description provision of 35 U.S.C. 112, first paragraph for the reasons set forth below.

The claimed properties of the putative 98 kD protein can only be determined empirically by actually making every nucleic acid that encodes the recited fragments/variants and testing each to determine whether it encodes a protein having the particularly disclosed properties of an 98kDprotein. As noted in the Guidelines at Section I.A (2) there is no written description support for fragments/variants of SEQ.ID.NO: 14 or 1, vaccine vectors comprising said sequences,

pharmaceutical composition and a method of preventing or treating Chlamydial infection as claimed.

Applicants specification proposes the converse, yet still does not meet the requirements for an adequate written description of the claimed invention. Applicants propose that the skilled artisan is to modify a known nucleic acid sequence encoding a known protein sequence and that modification would still describe applicant's invention as a 98kDprotein as disclosed. The 98kD outer membrane protein is uncharacterized by this specification and is not asserted to belong to any known family of proteins. The protein has specific biological properties dictated by the structure of the protein and the corresponding structure of the structural gene sequence which encodes it. There must be some nexus between the structure of a gene sequence and the structure of the protein encoded, and the function of that encoded protein. However, similar function cannot be predicted from the modification of the structure of the gene or in this case the gene encoding the protein. Applicants have not shown that, by modifying a reference sequence encoding a reference polypeptide as claimed, will automatically predict the production of a 98kDouter membrane protein as disclosed. While it is true that, due to the nature of codon degeneracy, applicant may take a reference sequence and modify that sequence to be a different nucleic acid sequence, yet still have that nucleic acid encode the same putative 98 kD protein. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotides encoding a representative number 98kDpolypeptides, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. With the exception of an isolated polynucleotide comprising the nucleic acid sequence SEQ ID NO: 1 and an isolated polynucleotide encoding the amino acid SEQ ID NO: 14, fragments thereof and associated, vectors, vaccines, fusions etc dependent thereon, the skilled artisan cannot envision the contemplated nucleotide sequences by the detailed chemical structure of the claimed polynucleotides and therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chugai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

35 U.S.C. 112 scope of enablement rejection maintained

8. The scope of enablement rejection of claims 1,2, 4-17, 25, 36-38 (in part) and 79-83 under 35 U.5.C. 112, first paragraph is maintained as set forth in the previous Office action.

The nature of the disclosed invention is preparing recombinant polypeptide from *C.pneumoniae*. The state of the art prior art in *C.pneumoniae* is devoid of making or using recombinant fragments as claimed. Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid sequences (i.e. fragments) for different aspects of biological activity cannot be predicted a priori and must be determined empirically on a case-by-case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page1-6). The art specifically teaches that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a

single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological-activity of the protein (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., Molecular and Cellular Biology, 8(3): 1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (Mol. Microbiol. 1991, 5(7): 1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which produces proteins that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of structural components to both biological function and immunological recognition. Thus, it is apparent that change in a peptide can lead to loss of binding property of that peptide.

The specification provides no working examples demonstrating (i.e., guidance) enablement for an isolated nucleic acid encoding polypeptide variants/fragment of SEQ.ID.NO: 14 or variants/ fragments of SEQ.ID.NO: 14 must be considered highly unpredictable, requiring a specific demonstration of efficacy on a case-by-case basis. Thus, the specification fails to provide an enabling disclosure for using variants/ fragments of SEQ.ID.NO: 14 or isolated nucleic acid SEQ.ID.NO: 1 because it fails to provide guidance how a variants/ fragments of SEQ.ID.NO: 14 or fragments of SEQ.ID.NO: 1 are useful in diagnosing *C.pneumoniae* infection The specification provides no disclosure how a variants/ fragments of SEQ.ID.NO: 14 or SEQ.ID.NO: 1 may be used as a target for *Chlamydia* infection because it fails to provide guidance whether this variants/ fragments of SEQ.ID.NO: 14 or SEQ.ID.NO: 1 has the ability to bind to *C.pneumoniae* patient's sera obtained from various clinical samples. Therefore, the skilled artisan would not be able to use such broadly claimed variants/ fragments of SEQ.ID.NO: 14 or SEQ.ID.NO: 1

With respect to claimed composition as a vaccine composition or a pharmaceutical composition, the specification does not provide how would an artisan have used the vaccine vector comprising an isolated nucleic acid molecule comprising the nucleic acid sequence as set forth in SEQ ID NO: 1, an isolated nucleic acid molecule encoding the amino acid sequence as set forth in SEQ.ID.NO: 14, the protein and its variants to treat or prevent the infection against *Chlamydia* (including infection caused by C.pneumoniae or C.trachomatis). Furthermore, the patient's sera have not yet been shown to identify the claimed protein or its fragments in an *in vitro* assay. The specifications does not ensure that the protein or its variants would be able to successfully generate a protective immune response to treat or prevent an infection because the state of the art suggests that the protective immune response to infection with *Chlamydia* is associated with antibody reactivity to species specific, serovar specific and serogroup specific determinants on the major outer membrane proteins (see Allen et al, Journal of Immunology 1991, 147; 674-679 and Batteiger et al 1996, Infection and Immunity , 64; 2839 - 2841). Murdin et al (J. Infectious Diseases, 2000, 181, Suppl. 3:S552-S557) teaches that although considerable progress toward developing a C. pneumoniae vaccine has been made in the last 1-2 years, a true candidate vaccine does not yet exist (p. 5554). The development of a candidate vaccine requires the determination of both protective antigens and a safe, effective, formulation of those antigens." (p. S554). Murdin et al teaches that antigen formulation remains an area in which much information is still needed, including what constitutes a protective immune response to C. pneumoniae in humans, how to express recombinant antigen and how

to formulate them to elicit a protective response in humans (see page 554). Therefore, the protective role of antibodies to claimed nucleic acid encoding polypeptide SEQ.ID.NO: 14 or isolated nucleic acid SEQ.ID.NO: 1 appears to be critical for protection and the specification fails to disclose such studies and is yet to be studied. Further, immune response generated by claimed DNA a, would be able to treat any and all Chlamydia infections as claimed are left for experimentation. Further, the specification provides no working examples demonstrating (i.e., guidance) enablement for any *in vivo* use *of* the claimed vaccine vectors or fragments/ variants thereof. However, it is unclear whether this approach is feasible in the treatment of Chlamydial infections using the claimed nucleic acid encoding SEQ.ID.NO: 14 or isolated nucleic acid SEQ.ID.NO: 1 has not been shown to treat even an ongoing Chlamydia infection. Thus, the claimed composition for the treatment or prevention of Chlamydial infection (including infection caused by C.pneumoniae or C.trachomatis) must be considered highly unpredictable, requiring a specific demonstration of efficacy of the claimed protein in treating specific Chlamydia infection.

With respect to Claim 36, the specification does not provide an enabling disclosure for the treatment of Chlamydia in patients following direct administration of any and all nucleic acid constructs of the instant invention i.e., a method of treating or preventing Chlamydia infection. The specification does not provide guidance for the construction of nucleic acid vectors which are adenoviral vectors, retroviral vectors, or herpes virus vectors, or the kinds of promoters that are functional in retroviral vectors or plasmid based vectors. The specification also does not provide guidance for the dosage, or the routes of delivery of any and all nucleic acid constructs to a patient wherein the level of expression of the encoded fusion protein results in a therapeutic effect on the patient's Chlamydial infection. At the time of filing, gene therapy of Chlamydia using the direct administration of DNA was considered to be highly unpredictable. Verma et al state that, "[t] he Achilles heel of gene therapy is gene delivery and that, most of the approaches suffer from poor efficiency of delivery and transient expression of the gene (Verma et al, 1997, Nature, Vol. 389, page 239, column 3, paragraph # 2). Miller et al (The FASEB Journal 1995, 9: 190-199) concurs, stating that, a difficulties in getting genes transferred efficiently to target cells- and getting them expressed- remain a nagging problem for the entire field," and that, many problems must be solved before gene therapy will be useful.

The applicant's specification does not demonstrate a correlation between the level of antibody generated using the claimed compositions in a method of preventing or treating infection i.e., therapeutic effect on a patient suffering from Chlamydial infection. Further, the specification does not provide guidance as to the level of anti-idiotypic antibody necessary to delay infection, decrease existing bacterial infection, or prevent the spread of infection. Therefore, it is concluded that the specification as filed is not enabling for the claimed vaccine vectors, vaccine compositions, pharmaceutical composition and a method of treating or preventing infection as filed and an artisan would not have been able to practice the invention without undue experimentation.

Applicant continues to traverse the rejections. However, applicant's arguments 2/27/06 have been fully considered but they are not deemed to be persuasive.

Applicant states that the specification at various pages discloses (for example: pages 12-13, 18- 21, 37, 42 and 44 etc) immunogenic fragments of SEQ.ID.NO: 14 or 1 and thus

applicants are in possession of the claimed invention. Applicant also cites several case laws and BPAI (Board of Patent appeals and interferences, USPTO) decisions as a supporting evidence for written description and enablement issues.

The examiner carefully reviewed the cited material of record and understands that the specification discloses an isolated nucleic acid comprising the nucleic acid sequence SEQ.ID.NO: 1 Or an isolated nucleic acid molecule, SEQ.ID.NO: 1 encoding the amino acid sequence SEQ.ID.NO: 14 Or an isolated nucleic acid consisting of the nucleic acid sequence SEQ.ID.NO: 1 encoding the amino acid sequence which is 95% identical to the amino acid sequence of SEQ.ID.NO: 14 Or an isolated nucleic acid consisting of nucleic acid sequence , SEQ.ID.NO:1 encoding an immunogenic polypeptide fragment **consisting** of 12/50 consecutive amino acids of SEQ.ID.NO: 14 Or an isolated nucleic acid consisting of 38/ 100 consecutive nucleotides of SEQ.ID.NO:1 and therefore, applicants are in possession said isolated nucleic acid molecules. However, the specification does not disclose an isolated nucleic acid molecules as claimed with open claim language i.e., **an isolated nucleic acid comprising a nucleic acid sequence which encodes a polypeptide SEQ.ID.NO: 14 Or an isolated nucleic acid comprising a nucleic acid sequence SEQ.ID.NO: 1 Or encoding a polypeptide which is 95% identical in amino acid sequence of SEQ.ID.NO: 14 Or an isolated nucleic acid comprising a nucleic acid sequence, SEQ.ID.NO: 1 encoding an immunogenic polypeptide fragment consisting of 12/50 consecutive amino acids of SEQ.ID.NO: 14 Or an isolated nucleic acid comprising a 38/ 100 consecutive nucleotides of SEQ.ID.NO:1** because the claimed nucleic acid molecule with open claim language are broader than SEQ.ID.NO: 1 or SEQ.ID.NO: 14 . Therefore, the rejection is maintained as the specification fails to teach the claimed polypeptides and do not satisfy the written description or enablement guidelines because an isolated nucleic acid comprising SEQ.ID.NO: 1 or 14 plus unknown

unlimited nucleic acids that would result in an unknown nucleic acid having no structure or function. Further, recitation of open language " comprising " in the claims does not limit to the fragment consisting of 12 /38/50/100 consecutive nucleic acids of SEQ.ID.NO: 1 or nucleic acid encoding SEQ.ID.NO: 14 but reads on fragments of SEQ.ID.NO: 14 or 1 plus other unknown and unlimited nucleic acids and are not supported by the present specification.

Applicant states that the instant application provides full disclosure of the nucleic acid sequence SEQ.ID.NO: 1 or 1 4 ii) substantial guidance has been provided in specification and also one of ordinary skill in the art has ability and skill to produce fragments iii) the examiner's concerns regarding "unlimited and unknown amino acids" of SEQ.ID.NO: 14 or 1 are not correct and the claims do not encompass unlimited and unknown nucleic acids" because applicant is claiming immunogenic fragments of SEQ.ID.NO: 14 or 1 and claims are properly enabled.

The examiner understands that the specification discloses an isolated nucleic acid comprising the nucleic acid sequence SEQ.ID.NO: 1 Or an isolated nucleic acid molecule, SEQ.ID.NO: 1 encoding the amino acid sequence SEQ.ID.NO: 14 Or an isolated nucleic acid consisting of the nucleic acid sequence SEQ.ID.NO: 1 encoding the amino acid sequence which is 95% identical to the amino acid sequence of SEQ.ID.NO: 14 Or an isolated nucleic acid consisting of nucleic acid sequence, SEQ.ID.NO: 1 encoding an immunogenic polypeptide fragment **consisting** of 12/50 consecutive amino acids of SEQ.ID.NO: 14 Or an isolated nucleic acid consisting of 38/ 100 consecutive nucleotides of SEQ.ID.NO:1. However, the specification does not disclose broadly claimed nucleic acid and are not supported by the present specification.

Please note the BPAI decisions are made in each application based on its merits and are not considered for other applications. However, the examiner noted the relevance and responding accordingly with the published art in the field.

The examiner understands that fragments consisting of short peptides are used for raising antibodies and in subunit vaccine preparation. Here, the issue is whether an isolated nucleic acid **comprising a nucleic acid sequence SEQ.ID.NO: 1 or encoding a polypeptide comprising an amino acid sequence SEQ.ID.NO: 14 Or** its fragments have been supported by the specification or not. As discussed above, claims are not enabled for isolated nucleic acid molecule fragments. The art (see for example: Niman et al, PNAS, USA1983, Vol 80:4949-4953, table 2) clearly indicated that specific isolated peptide **consisting of** five or ten amino acids can induce antibody response and recognize the full length protein and thus supporting the examiner's position (i.e., **immunogenic fragment consisting of 12/50consecutive amino acids of SEQ.ID.NO: 14 or** an isolated nucleic acid **consisting of 38/100 consecutive nucleic acids of SEQ.ID.NO: 1**. Further, the art teaches longer the peptide, the lower will be the purity of the peptide and therefore, synthesis of peptides that are longer than 6 residues should be avoided (see Current Protocols in Immunology, 1997 unit 9.7.5, third paragraph under assessing peptide sequences). Reece et al, 1994, J. Immunol, Vol 172 , 241 teaches that many epitopes (see abstract) would be missed if the peptides used were long (31mer, Table 2). Thus, the art teaches immunogenic fragment consisting of 12 consecutive amino acids of SEQ.ID.NO: 14 are suitable for raising antibodies etc but not the polypeptide **comprising** an immunogenic fragment of **"at least"** 12 consecutive amino acids as it reads on unknown fragments that are broader than SEQ.ID.NO: 14 having no function.

The limitation "at least " in the claims does not limit to 12/50 consecutive amino acids because it has no upper limit and thus reads on fragments having more than 12/50 amino acids in length. Similarly the limitation "comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. Therefore, the claimed polypeptides are

broader. Hence examiner's concern regarding the language used is important in claiming isolated polypeptides/fragments.

Evidentiary references as discussed above clearly indicated the use of short 12 – mer isolated peptide **consisting** of 12 consecutive amino acids as immunodominant regions of the antigen. Therefore, an isolated nucleic acid molecule consisting of the nucleic acid sequence which encodes the **immunogenic fragment consisting of 12/50consecutive amino acids of SEQ.ID.NO: 14 or** an isolated nucleic acid **consisting of 38/100 consecutive nucleic acids of SEQ.ID.NO: 1 are enabled**. Absent such demonstration, the invention would require undue experimentation to practice as claimed.

With respect to the DNA vaccine, Applicants submitted a declaration under 37 C.F.R. 1.132 from inventor Murdin. Dr. Murdin declares that the publications cited by the examiner Allen et al. J. Immun. 1991, Battereiger et al. 1996 and Murdin et al. 2000, in the enablement rejection do not relate to his personal knowledge of scientific results obtained by Aventis Pasteur Limited, in the field of DNA vaccines against Chlamydia. Rather, the publication relates only to General knowledge known to skilled workers who do not have access to scientific results obtained at Aventis Pasteur Limited. In Dr. Murdin's opinion, the results obtained at Aventis Pasteur Limited indicate that at least one true candidate exists against Chlamydia, i.e. the vaccine which is subject of the present application. Therefore, Allen et al. Battereiger et al and Murdin et al. 2000 do not accurately show the state of the art as it pertains to the instant application. In addition applicant also provided articles of record on cancer vaccines and growth factor using DNA as a candidate vaccine.

The examiner carefully reviewed and fully considered the Declaration as well as the articles but they are not deemed to be persuasive because neither the Declaration of record nor the art provided by the applicant show any evidence or support that DNA vaccines for

Chlamydial infection are routine in the art. Further, the claimed composition for the treatment or prevention of Chlamydial infection (including infection caused by C.pneumoniae or C.trachomatis) has not been show to be protective. Therefore, the DNA vaccine must be considered highly unpredictable, requiring a specific demonstration of efficacy of the claimed protein in treating specific Chlamydia infection. Therefore, the rejection is maintained.

Claim Rejections - 35 U.S. C. § 112, second paragraph maintained

9. The rejection of claims 9-11 and 13 under 35 U.5.C. 112, second paragraph is maintained as set forth in the previous office action.

Claims 9-11 are vague and indefinite for the recitation of "second polypeptide. It is not clear what are the metes and bounds this term since first peptide has not been recited in the claims? Claim 13 is vague in reciting "additional polypeptide ". It is not clear what are the metes and bounds of additional polypeptide, which enhances the immune response to at least one polypeptide? As written it is confusing and not clear whether the second polypeptide or additional polypeptide are same or different?

Applicant's arguments 2/27/06 have been fully considered but they are not deemed to be persuasive.

Applicant states that the specification describes the (pages 27, 31 and 40) components of fusion polypeptide and additional polypeptide. Therefore, the rejection should be withdrawn.

The examiner has reviewed the specification and understands that heterologous polypeptide is a component of fusion polypeptide and additional polypeptide. Therefore, applicant is advised to amend the claim so that the metes and bounds of the claims will be clear.

Status of Claims

10. No claims are allowed.

Conclusion

11. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile

must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.